



RECEIVED

DEC 04 2003

TECH CENTER 1600/2900

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q67507

Keiichi KAWAI, et al.

Appln. No.: 10/018,745

Group Art Unit: 1616

Confirmation No.: 2602

Examiner: Dameron L. JONES

Filed: December 21, 2001

For: METHOD OF THE ADMINISTRATION OF DRUGS WITH BINDING AFFINITY FOR PLASMA PROTEIN AND PREPARATION TO BE USED IN THE METHOD

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, along with a copy of an International Search Report in a counterpart application from the International Bureau.

The present Information Disclosure Statement is being filed (without a Statement Under 37 C.F.R. § 1.97(e)) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of

INFORMATION DISCLOSURE STATEMENT
U.S. Appln. No.: 10/018,745

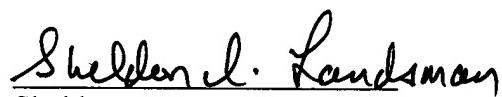
Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore a check for the fee of \$180.00 under 37 C.F.R. § 1.17(p) is attached.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, applicants enclose herewith an English language International Search Report from the International Bureau, including that portion of the International Search Report indicating the degree of relevance found by the International Searching Authority. In addition, applicants note that the cited Matsui et al Article contains an English-language abstract.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,


Sheldon I. Landsman
Sheldon I. Landsman
Registration No. 25,430

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: November 24, 2003

RECEIVED

Substitute for Form 1449 A & B/PTO

EDD 7/2000

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

| | |
|------------------------|-------------------|
| Application Number | 10/018,745 |
| Confirmation Number | 2602 |
| Filing Date | December 21, 2001 |
| First Named Inventor | Keiichi KAWAI |
| Art Unit | 1616 |
| Examiner Name | Dameron L. JONES |
| Attorney Docket Number | Q67507 |

Sheet

1

of 1

| U.S. PATENT DOCUMENTS | | | | |
|-----------------------|-----------------------|-----------------|--------------------------------------|---|
| Examiner Initials* | Cite No. ¹ | Document Number | | Name of Patentee or Applicant of Cited Document |
| | | Number | Kind Code ² (if known) | |
| | | US | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Translation ⁶ |
|--------------------|-----------------------|---------------------------|---------------------|--------------------------------------|--------------------------------|--|--------------------------|
| | | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | | | |
| | | | | | | | Abstract |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | Translation ⁶ |
|--------------------|-----------------------|--|--------------------------|
| | | KAWAI, K. et al., "Competitive displacement of 99mTc-MAG3 serum protein binding in in-vitro and in-vivo.", Journal of Labelled Compounds and Radiopharmaceuticals, June 1999, Vol. 42, SUPPL. 1, pp.S584-S586. | |
| | | BUBECK, Berand et al., "Pharmacokinetics of Technetium -99m-MAG3 in Humans.", The Journal of Nuclear Medicine, 1990, Vol. 31, No. 8, pp. 1285-1293. | |
| | | MATSUI, Mieko et al., "Application of fractional uptake method to 99mTc-ECD SPECT for quantification of brain perfusion using cardiac output index.", Kobe Daigaku Igakubu Kiyo, 1998, Vol. 58, No. 4, pp.191-196. | Abstract |
| | | IVARSEN, Per Ramloev et al., "Displacement of bilirubin from adult and newborn serum albumin by a drug and fatty acid.", Dev. Pharmacol. Ther., 1989, Vol. 12, No. 1, pp.19-29. | |
| | | BRIAND, C. et al., "Study of the interaction between human serum albumin and some cephalosporins.", Mol. Pharmacol. 1982, vol. 21, No. 1, pp. 92-99. | |
| | | SEMMES, Robin L.O. et al., "Nonlinear binding of valproic acid (VPA) and E-Δ2-valproic acid to rat plasma proteins.", Pharm. Res. 1990, Vol. 7, No. 5, pp.461-467. | |
| | | LOCKWOOD, Graham F. et al., "Pharmacokinetics of ibuprofen in man-III: Plasma protein binding.", J. Pharmacokinet. Biopharm. 1983, Vol. 11, No. 5, pp.469-482. | |
| | | ABDEL-RAHMAN M. et al., "Interaction between verapamil and vincristine binding to plasma proteins.", INTERNATIONAL JOURNAL OF CLINICAL PHARMACOLOGY, THERAPY, AND TOXICOLOGY, 1992, Vol. 30, No. 11, pp.536-537. | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.